Remarks/Arguments

Applicants have received and carefully reviewed the Office Action mailed September 29, 2009. Currently, claims 1, 4, 5, 8, and 28-33 have been rejected. With this Amendment, claims 1, 4, and 28 have been amended and claim 31 has been canceled. As such, claims 1, 4-5, 8, 28-30, and 32-33 remain pending. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 USC § 112

In paragraph 3 of the Office Action, claims 1, 4, 5, and 8 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. In particular, the phrase "the branch guidewire enclosure is bonded to the first tubular member only at the branch exit port" was rejected as not having proper support in the specification. While Applicants respectfully disagree, claim 1 has been amended to recite "the branch guidewire enclosure is bonded to the first tubular member only at the proximal end region of the branch guidewire enclosure". As amended, claim 1 is believed to comply with the written description requirement and withdrawal of the rejection is respectfully requested.

Claim Rejections – 35 USC § 103

In paragraph 5 of the Final Office Action, claims 28-33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (U.S. Patent No. 6,099,497) in view of Ischinger (U.S. Patent No. 6,682,556). After careful review, Applicants respectfully traverse this rejection.

Turning to claim 28, which recites:

> 28. (Currently Amended) A catheter comprising:
> a first catheter ~~proximal~~ tube including ~~extending from~~ a proximal end [[to]] and a distal end;
> a first distal tube having a proximal end region defining a proximal open end, the first distal tube being configured to receive a first guidewire;
> a second distal tube having a proximal end region defining a proximal open end, the second distal tube being configured to receive a second guidewire; [[and]]
> a balloon including a proximal waist and a distal waist, the proximal waist being coupled to the first catheter tube adjacent the distal end of the first catheter tube, and the distal waist being coupled to the first distal tube adjacent to the distal end of the first distal tube;
> a stent positioned about at least a portion of the balloon, wherein the second distal tube is configured to exit through a side opening in the stent; and

a bond material configured to bond the proximal end region of the first distal tube, the proximal end region of the second distal tube, and an intermediate region of the first catheter tube ~~having a proximal end and a distal end, the proximal end of the bond coupled to the distal end of the proximal tube, the distal end of the bond coupled to the first distal tube adjacent to the proximal open end~~ such that the proximal open end of the first distal tube remains open to define a first guidewire exit port[[,]] and ~~the distal end of the bond coupled to the second distal tube adjacent to the proximal open end such that~~ the proximal open end of the second distal tube remains open to define a second guidewire exit port.

Without conceding the correctness of the rejection, Applicants have amended claim 28 to further distinguish claim 28 from the cited reference. Nowhere do Adams et al. or Ischinger appear to disclose many elements of claim 28, including for example, "a balloon including a proximal waist and a distal waist, the proximal waist being coupled to the first catheter tube adjacent the distal end of the first catheter tube, and the distal waist being coupled to the first distal tube adjacent to the distal end of the first distal tube" or "a bond material configured to bond the proximal end region of the first distal tube, the proximal end region of the second distal tube, and an intermediate region of the first catheter such that the proximal open end of the first distal tube remains open to define a first guidewire exit port and the proximal open end of the second distal tube remains open to define a second guidewire exit port". For at least these reasons, claim 28 is believed to be patentable over Adams et al. in view of Ischinger. For similar reasons and others, claims 29-30 and 32-33, which depend from claim 28 and include additional distinguishing features, are believed to be patentable over Adams et al. in view of Ischinger.

In paragraph 8 of the Office Action, claims 1, 4, 5, and 8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (U.S. Patent No. 6,099,497) in view of Keith (U.S. Patent No. 6,273,879). After careful review, Applicants respectfully traverse this rejection.

Turning to claim 1, which recites:

1. (Currently Amended) A catheter system for positioning a stent at a vessel bifurcation, the catheter system comprising:

a catheter including a proximal end and a distal end, the catheter comprising:

a first tubular member including a proximal end and a distal end, the first tubular member defining an inflation lumen of the catheter and extending distally from the proximal end of the catheter;

a second tubular member defining a main guidewire lumen ~~extending proximally from a distal end of the second tubular member to a proximal end of the second tubular member~~, wherein the distal end of the second tubular member is a distal end of the catheter and the proximal end of the second tubular member

defines a main guidewire exit port, wherein the main guidewire lumen is configured to receive a main vessel guidewire therethrough, wherein the second tubular member is at least partially disposed within the inflation lumen of the first tubular member;

a balloon including a proximal waist coupled to the first tubular member adjacent to the distal end of the first tubular member and a distal waist coupled to the second tubular member adjacent to the distal end of the second tubular member;

a branch guidewire enclosure positioned alongside the first tubular member, wherein the branch guidewire enclosure defines a lumen configured to receive a branch vessel guidewire therethrough, the branch guidewire enclosure including a proximal end region having a proximal end and a distal end region, the [[a]] proximal end of the branch guidewire enclosure defining a branch guidewire exit port; and

a stent having a lumen and a side opening in a wall thereof, the stent positioned about at least a portion of the balloon, and wherein a distal portion of the branch guidewire enclosure is positioned through the lumen of the stent and exits at the side opening;

wherein the branch guidewire enclosure is bonded to the first tubular member only at the proximal end region of the branch guidewire enclosure ~~branch exit port~~, wherein the main guidewire exit port and the branch guidewire exit port are located proximal of the stent and distal of the proximal end of the catheter.

Nothing in Adams et al. or Keith et al. appear to disclose many elements of claim 1, including for example, "wherein the branch guidewire enclosure is bonded to the first tubular member only at the proximal end region of the branch guidewire enclosure, wherein the main guidewire exit port and the branch guidewire exit port are located proximal of the stent and distal of the proximal end of the catheter".

The Office Action initially appears to refer to Figure 14A as disclosing the features of claim 1 and then refers to Figures 14D, 17, and 18 as disclosing "wherein the branch guidewire enclosure is bonded to the first tubular member only at the proximal end region of the branch guidewire enclosure". However, nothing in Figures 14A, 14D, 17, or 18 appear to disclose the branch guidewire enclosure bonded to the first tubular member only at the proximal end region of the branch guidewire enclosure, which has a proximal end defining a branch guidewire exit port. Instead, as clearly shown in the Figure reproduced on page 4 of the Office Action pointing out the bond, the proximal end region of the branch guidewire enclosure of Adams does not have a branch guidewire exit port.

Further, Applicants submit that the Office Action appears to ignore the phrase "only at the proximal end region" or previous recitation of claim 1. Applicants note that "'All words in a

claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970)." (MPEP § 2143.03). Instead, the Office Action appears to interpret the phrase "bond portion" (which is not even recited in claim 1) broadly and, in the process, appears to ignore the term "only". For example, the Office Action concludes "Adams discloses the branch guidewire enclosure bonded to the first tubular member". However, nothing in this assertion suggests that Adams discloses the branch guidewire enclosure bonded to the first tubular member "only at the proximal end region" of the branch guidewire enclosure. Applicants submit that nothing in Adams et al. appears to teach, suggest, or disclose such a feature. Further, MPEP § 2111 states "The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999)". As such, Applicants submit that Office Action's interpretation of the phrase "only at the proximal end region" of claim 1 is clear error.

Further, the Office Action appears to conclude "Adams also discloses the guidewire ports being located proximal of the balloon. Therefore, the region of the bond portion is chosen to include the region where the tubes are bonded and the region where the ports are located". Again, Applicants submit that nothing in claim 1 as amended or prior to being amended included the phrase "bond portion". Instead, claim 1 recites "wherein the branch guidewire enclosure is bonded to the first tubular member only at the proximal end region of the branch guidewire enclosure, wherein the main guidewire exit port and the branch guidewire exit port are located proximal of the stent and distal of the proximal end of the catheter". Applicants submit that nothing in Adams appears to disclose a branch guidewire exit port where the branch guidewire enclosure is bonded to the first tubular member. For example, Figures 14A, 14D, 17, and 18 do not appear to show any branch exit port at the part of the catheter cited by the Office Action as the bond (see the marked up Figure on page 4 of the Office Action). Further, as noted by the Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006):

> "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness".

(Emphasis added; see page 14 of the April 30, 2007 Decision and MPEP § 2141.) The Court further stated:

> a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

(See page 14 of the April 30, 2007 Decision.). Applicants submit that the Office Action fails to provide the required articulated reasoning with some rational underpinning to establish a *prima facie* case of obviousness, but instead, provides merely conclusory reasons. Notably, the only apparent reason to modify Adams et al. in the manner suggested by the Office Action appears to come from Applicants' own specification, which is clearly improper.

Further, nothing in Keith et al. appear to remedy the noted shortcomings of Adams et al. Moreover, there appears to be no reason to modify the balloon disclosed in Figures 14D, 17, and 18 of Adams et al. to include "a proximal waist coupled to the first tubular member adjacent to the distal end of the first tubular member and a distal waist coupled to the second tubular member adjacent to the distal end of the second tubular member", as recited in claim 1. For these and other reasons, claim 1 is believed to be patentable over Adams et al. and Keith et al. For similar reasons and others, claims 4-5 and 8, which depend from claim 1 and include additional distinguishing features, are believed to be patentable over Adams et al. and Keith et al.

Conclusion

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Further examination and withdrawal of the rejections is respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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